IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

THIS DOCUMENT RELATES TO ALL CASES

DEFENDANT ACTAVIS INC., ACTAVIS TOTOWA LLC, AND ACTAVIS ELIZABETH, LLC'S BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION TO EXPAND THE SCOPE OF DISCOVERY

In the first days of this litigation, Plaintiffs' claims focused on injury caused by the purchase and ingestion of "double thick" Digitek® tablets. When none could be found that actually made it to market, Plaintiffs shifted the focus of their claims to injury caused by Digitek® tablets with dosages of the active ingredient digoxin different from the dosage stated on the labeling. Now – where neither the Digitek® documents produced, Plaintiffs' medical records, nor any test results produced to Defendants bear out this theory – Plaintiffs seek to broaden the scope of discovery in the hopes of using unrelated documents reflecting manufacturing issues concerning 106 other non-Digitek® products to infer dosage problems with Digitek®. (ECF No. 136.) They seek to broaden the scope of discovery under PTO #12 or, in the alternative, modify PTO #12 to allow for such discovery. Both arguments fail.

Under PTO #12, Plaintiff's motion should be denied because: 1) the broadened discovery they seek is not reasonably related to the Digitek® manufacturing process; and 2) Plaintiffs have failed to otherwise show good cause to open discovery up to the entire panoply of products manufactured at defendants' Little Falls facility. Their alternative request to modify PTO #12 – to include discovery of the other 106 products – should likewise be denied on FRE 401 relevancy grounds on which both PTO #12 and the applicable case law are based. As

established below, plaintiffs' arguments are based solely on conclusory allegations. Defendants' response is based on controlling legal standards and affidavit testimony which, together with plaintiffs' complaint, establish the following facts:

1. Plaintiffs' allegations are limited to one prescription medicine – Digitek®. Plaintiffs do not allege injury as a result of any of the other 106 products.

2. The manufacturing process for Digitek® is entirely different from the processes used to make other drugs.

3. It would be unduly burdensome and expensive to permit the limitless expansion of the discovery plaintiffs seek. The cost to produce Digitek®-only documents is conservatively estimated at $6,000,000; the cost to expand production as plaintiffs request would raise costs 3-5 fold – brimming at approximately $30,000,000 for a fishing expedition in documents that will ultimately be inadmissible as irrelevant. Further, any expansion would substantially delay the Case Management Order.

In short, opening up the discovery in this case to the distinct manufacturing processes of 106 different drugs, processes unrelated to the Digitek® manufacturing process, does not remotely assist either the parties or the Court in establishing or assessing the merits of Plaintiffs' Digitek® claims. It instead will adversely affect the progression of this litigation, and deplete all resources available to bring the Digitek® claims to a speedy and efficient resolution. Plaintiffs' motion should therefore be denied, and the relief requested in Defendants' Motion to Quash the Gibraltar Subpoena should be granted. (ECF No. 134.)

I. PERTINENT FACTS

A. Actavis Totowa's Little Falls Facility and the 2008 Recalls.

Actavis Totowa, a generic pharmaceutical company, manufactured 108 different pharmaceutical products at its Little Falls facility as of 2008 consisting of 64 unique drugs, some with multiple dose strengths. One of the 64 was Digitek®. It was sold in two different dose strengths. Actavis Totowa recalled Digitek® to the consumer level on April 25, 2008 due to the possibility of double thick tablets entering the market. Later in 2008, Actavis Totowa decided to

voluntarily recall to the retail level, only, all other products it manufactured. There was no concern about double thick tablets with any of these other products.

B. The Allegations in This Case are Limited to Digitek® "Dose" Issues; None of the Plaintiffs in This Litigation Allege Injury as a Result of Purchasing or Ingesting Any One of the Other 106 Actavis Products.

Digitek® is the only pharmaceutical product at issue in this litigation. Plaintiffs filed suit on behalf of persons "who were prescribed, purchased, and ingested Digitek® (Digoxin)." (ECF No. 73 at ¶ 2.) All of Plaintiffs' claims pertain to Digitek®. (ECF No. 73 at ¶¶ 3-9, 12-17, 54-182.) No Plaintiff claims that he/she purchased, ingested, or suffered harm from any pharmaceutical other than Digitek®. (ECF No. 73.) Specifically, Plaintiffs allege that Digitek® was unreasonably dangerous to its users because the amount of digoxin, the active ingredient in Digitek®, was not consistent among Digitek® tablets and was not consistent with the dosage stated on the Digitek® label. (ECF No. 73 at ¶¶ 57, 64, 71, 78, 80, 84, 102, 105, 121, 129.)

C. Defendants Have Collected and Are Producing Extensive Documents Regarding Digitek®.

Actavis is producing documents on a rolling basis in accordance with the schedule set forth in PTO #16. To date, Actavis has produced more than 30,000 pages of documents including records relating to more than 65 of the 153 recalled batches, with another 50 batches set for production on June 23. Actavis has also produced other key documents, including the Digitek Annual Reports and Annual Product Reviews for 5 years, the distribution agreement between Actavis and Mylan, and FDA regulatory correspondence (and Actavis' responses) regarding the Little Falls facility for 2006 - 2008. Perhaps most importantly, Actavis has produced records relating to the *only* batch of recalled Digitek where any defectively thick tablets were found during manufacturing, and has produced the reports and documents setting forth those circumstances in great detail.

D. Plaintiffs Have Failed to Make Any Showing That Double Thick Tablets Reached Market, or That Any Plaintiff Purchased or Ingested an "Out-of-Specification" Tablet.

Although Plaintiffs allege that Digitek® tablets have "excess levels of active ingredient" (ECF No. 73 at ¶ 84), no Plaintiff has come forward with a double thick tablet and, to date, no Plaintiff has produced any lab testing showing an out-of-specification Digitek® tablet. As a result, Plaintiffs have failed to make any threshold showing of "defective" Digitek® reaching market. At a March 27, 2009 Case Management Conference in New Jersey, Judge Harris asked all of the assembled Plaintiffs' lawyers if any of them had seen an "elusive double-thick tablet." (Transcript of Case Management Conference at 53-54, Mar. 27, 2009 (Exh. A).) None had.

II. LEGAL ISSUES PRESENTED

1. The first legal issue presented is whether Plaintiffs have made a "good cause" showing that manufacturing process information about the 106 other drugs is reasonably related to the Digitek® manufacturing process. By way of background, the parties and the Court previously agreed that Defendants should redact information regarding non-Digitek® products. On February 5, 2009, the Court entered a Stipulated Protective Order – Pretrial Order #12 (*see* ECF No. 71) ("Protective Order" or "PTO #12") – which entitles Defendants to redact "[a]ny information relating to products other than Digitek®, unless manufacturing information about a product other than Digitek is reasonably related to Digitek manufacturing." (ECF No. 71 at II.F.4.) If Plaintiffs wish to seek information relating to products other than Digitek®, they must move the Court for an order compelling production, and they must show good cause. (ECF No. 71 at II.F.) That is what Plaintiffs now advance – that there is a reasonable relationship between the Digitek® manufacturing process and the manufacturing processes of the other 106 products made at the Little Falls facility. As shown below, this position is incorrect, and has no basis in fact.

2. In the alternative, Plaintiffs seek to revise PTO #12 to expand the scope of discovery to include all 106 products manufactured at the Little Falls facility. As shown below, the Court should deny this request under Federal Rule of Civil Procedure 26(b)(1) and Federal Rule of Evidence 401 because Plaintiffs' request seeks irrelevant, and ultimately inadmissible documents.

III. LAW AND ARGUMENT

A. Under PTO #12, Plaintiffs are Not Entitled to Discovery of Manufacturing Process Information Regarding Actavis Totowa's 106 Other Products Because the Information is Not "Reasonably Related" to the Digitek® Manufacturing Process.

Plaintiffs seek *any and every document* for *all* manufacturing processes of *every* product line at the Little Falls facility. (ECF No. 136 at 9.) But they have not shown that the manufacture of even a single non-Digitek® product is reasonably related to the manufacture of Digitek®. In fact, Plaintiffs have not made a single specific showing that the manufacture of any product is reasonably related to another. Rather, they simply conclude that all 106 other product manufacturing processes are reasonably related to the Digitek® manufacturing process when, in fact, just the opposite is true.

1. The Manufacture of Digitek® is a Distinct Process That Involves a Unique Set of Ingredients, Specifications, and Equipment.

The manufacture of Digitek® is unlike the manufacture of any other product at the Little Falls plant. As to ingredients, none of the 106 non-Digitek products contain digoxin, the active pharmaceutical ingredient in Digitek®. (Affidavit of Richard Dowling ¶ 10, attached as Exh. B.) Digoxin and only one other active pharmaceutical ingredient were received from suppliers in sealed plastic bottles; every other active pharmaceutical ingredient was received from suppliers in fiber drums. (*Id.*, ¶ 11.) The other ingredients of Digitek® are corn starch, croscarmellose sodium, lactose hydrous impalpable, starch pregelatinized, mircrocrystalline cellulose, lactose anhydrous, stearic acid and silicon dioxide. (*Id.*, ¶ 12.) Digitek® has a unique, FDA-approved

formula: the combination, weight, and blend uniformity of the raw materials is unique to Digitek®. (*Id.*)

As to equipment, Actavis uses a unique configuration of equipment to manufacture Digitek®. It is the only product that uses three blenders: a V-shaped blender, a portable blender, and a 50 cubic foot blender. (*Id.*, ¶¶ 27, 33.) The portable blender was used exclusively to blend Digitek®. (*Id.*, ¶ 31.) The 50 cubic foot blender was used to manufacture Digitek® and only one other product. (*Id.*, ¶ 32.) Digitek® is produced using a tablet press specifically customized for its production. (*Id.*, ¶¶ 14-20.) Each time Digitek® is manufactured, the Stokes BB2 45 station press is customized using very unique "tooling" – punches and dies – designed exclusively for manufacturing Digitek®. (*Id.*, ¶¶ 14-18, 21-22.) During 2005-2008, there was very little overlap between the equipment used to make Digitek® and the equipment used to make any of the other 106 products. (*Id.*, ¶ 28.) Of the other 106 products manufactured at the Little Falls facility during 2005-2008, only 10 products required use of equipment that was also used to make Digitek® (*Id.*, ¶¶ 28, 36.)

Aside from ingredients and equipment, Digitek® is manufactured, tested, and inspected in accordance with a set of FDA-approved specifications unique to Digitek®. Digitek® tablets are dissolved and chemically tested to check for dose uniformity and stability using FDA-guided specifications unique to Digitek®. (*Id.*, ¶¶ 38-39.) At the compression stage, both the press operator and the quality assurance employees inspect Digitek® tablets for visual appearance, weight, thickness, and hardness, using specifications unique to Digitek®. (*Id.*, ¶¶ 37, 39.) Every piece of equipment is reassembled, tested, and precisely calibrated to achieve and demonstrate compliance with the unique specifications for each individual product. (*Id.*, ¶¶ 24-25.) In every meaningful way, the manufacture of Digitek® is distinct from the manufacture of every other product made at Little Falls. (*Id.*, ¶¶ 42-43.)

2. Plaintiffs Have Not Shown That the Manufacture of Even a Single Non-Digitek® Product is Reasonably Related to the Manufacture of Digitek®.

Plaintiffs claim that the Digitek® manufacturing process is "closely intertwined," "intermingled," "indistinguishable," and "commingled" with the manufacturing process each of the 106 other products. (ECF No. 136 at 1, 6). Plaintiffs' sole support for this proposition is that: 1) the employees at the Little Falls facility involved in making Digitek® are also involved in the manufacture of the other 106 products made at the same facility; and 2) these employees use some of the same equipment to make Digitek® that they use to make other products. (ECF No. 136 at 2-3.) From these utterly insignificant facts, plaintiffs conclude that all manufacturing processes are reasonably related. But the gap in the argument is plain – they offer no evidence to actually establish any reasonable relationship between the Digitek® manufacturing process and any other product.

Defendants, conversely, have offered clear, specific testimony and evidence showing that the manufacturing process for Digitek® is unique in virtually all respects and has no reasonable relation to the manufacturing process for any other drug manufactured at Little Falls. Though plaintiffs claim to be "shocked" that some equipment can be cleaned, disassembled, and adjusted to manufacture more than one product, this fact is unremarkable. (ECF No. 136 at 6.) Like any other pharmaceutical manufacturer, Actavis owns and operates some equipment that can be disassembled, cleaned, reassembled, and calibrated to manufacture more than one product. This type of organizational structure and multi-functionality of equipment is common practice in the pharmaceutical industry. There are not dedicated teams to manufacture separate products; that is not a common practice in the industry, and indeed defies logic and common sense. (Dowling Aff., ¶ 44.) In short, plaintiff's "shock" has no basis in industry standard or practice, and certainly does not establish good cause.

To be clear, Digitek® is never commingled with any other product at any point in time during the manufacturing process. (*Id.*, ¶¶ 7-41.) While Plaintiffs further claim that "[a]ll equipment and all personnel were interchangeably utilized to manufacture all products," (ECF No. 136 at 6), this is both untrue and misleading. As noted, some equipment may be used to make more than one product, but the equipment is disassembled, sanitized, and set up according to specifications unique to each product. (Dowling Aff., ¶¶ 23-26.) Additionally, personnel are not interchangeable: employees in the blending department blend the digoxin; employees in the compression department operate the tablet presses; trained quality control personnel inspect the Digitek® tablets. (*Id.*, ¶ 44.) Again, this is industry standard, not "good cause" to open the discovery in this matter to every manufacturing process for all 106 drugs at Little Falls.

Last, Plaintiffs claim that two warning letters from the FDA somehow establish a "reasonable relationship" between the manufacture of Digitek® and every one of the 106 other products manufactured at Little Falls. (ECF No. 136 at 4-5.) The first letter they cite, an August 15, 2006 letter (Plaintiffs' Exh. E), has absolutely nothing to do with manufacturing procedures. It deals exclusively with observations about adverse reaction reporting. Plaintiffs' assertion that the letter refers to "a number of manufacturing violations" is simply not true. (ECF No. 136 at 4.)

The second letter, an August 1, 2007 warning letter (Plaintiffs' Exh. F), at least deals with manufacturing issues. But there is only the briefest of references to Digitek® (and only to one dosage strength), and that reference is in regard to a "cleaning validation." (*Id.*, ¶ 7(a).) There is no reference in this letter to double thick, increased dosage, or out-of-specification issues with Digitek®. (*Id.*) Nor is there any reference to double thick problems with any other product. Moreover, these letters do not remotely suggest that the manufacture of one product is "reasonably related" to another. A drug having too much or too little active pharmaceutical

ingredient is a unique problem. It is not the same problem as stability failure, hardness issues, packaging problems, a paperwork issue, or a failure to investigate more specifically.

In short, Plaintiffs' discovery should be reasonably limited to the allegations of their Complaint, all of which concern the manufacture of Digitek®, and Digitek® only. Stated another way, the "subject matter" of this action is whether any Plaintiffs received Digitek® that had too much or too little digoxin, not *any and every manufacturing process* at the Little Falls plant. *See, e.g., State of Missouri ex rel. General Motors Acceptance Corporation v. Standridge*, 181 S.W.3d 76, 78 (Mo. 2006) (en banc) (trial court abused its discretion where discovery was not limited to the "parameters" of the counterclaim).

B. The Court Should Not Expand the Scope of Discovery or Modify PTO #12 to Include the Discovery of the Manufacturing Processes of the 106 Other Products Because Such Discovery is Neither Relevant Nor Reasonably Calculated to Lead to the Discovery of Admissible Evidence.

Should Plaintiffs be precluded from expanding the scope of discovery to all manufacturing processes at Little Falls under the terms of PTO #12, they request – in the alternative – that the Court to modify PTO #12 to allow for such discovery. (ECF No. 136 at 6-9.) Because Digitek® is the only pharmaceutical product at issue in this litigation, and because none of the 106 other products have an alleged defect of too much or too little digoxin or other active pharmaceutical ingredient, discovery of the 106 other products is not "reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). That is, discovery of the 106 other products would not have "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable." Fed. R. Evid. 401. Indeed, PTO #12, and the applicable case law discussed below, are rooted in FRE 401 relevancy principles.

As described in detail above, the manufacture of Digitek® involves a unique set of ingredients, specifications, and equipment. Actavis did not make any other product that included digoxin. Digitek® is never commingled with any other product at any point during the manufacturing process. Data and information relating to any product other than Digitek® will provide no insight into any aspect or characteristic of the manufacture of any Digitek® batch. (Dowling Aff. ¶¶ 7-41.)

Judge Harris, sitting in the Superior Court of New Jersey, has already opined about the over breadth of Plaintiffs' request. At a March 27, 2009 case management conference, Plaintiffs' counsel conceded that he had never seen a double thick tablet but had heard rumors of one; Plaintiffs' counsel then expressed his desire to discover "what happened at the plant that wasn't in FDA compliance." (Transcript of Case Management Conference at 56.) Judge Harris called this "the archetypal fishing expedition." (*Id.*) As a presage to Plaintiffs' instant motion to expand the scope of discovery, Judge Harris then offered the following example:

> And they go [to] a plaintiff's lawyer and say gee, I had a bad incident here, test it, Oh, my God, you have Coumadin poisoning, well, now I want to go into the Coumadin plant, I want to check all of their warfarin specifications.
>
> I mean, it sounds absurd and silly, but I think you'd want a little bit more than you've got here. I'm not suggesting you're acting in bad faith but, you know, a lot of whispers are in the wind in this thing that don't really mean too much.

(*Id.* at 57.) Even more overreaching is the request here – Plaintiffs allege manufacturing defects in Digitek®, yet demand discovery of the manufacturing specifications and processes of Oxycodone, Betaxolol, and Hydroxyzine, in addition to more than one hundred other products. (*See* ECF No. 136 at 9) (seeking "information relating to all manufacturing processes for all product lines produced at the Little Falls plant.") Judge Harris concluded: "I'm not going to allow what I'll call free-ranging discovery." (*Id.* at 58.)

The Court's reasoning in *In re Richardson-Merrell, Inc. v. Bendectin Products Liability*, 624 F. Supp. 1212, 1241 (S.D. Ohio 1985) explains why the scope of discovery in this action should be limited to Digitek®. In *Richardson-Merrell*, plaintiffs brought a product liability action alleging injuries caused by the drug Bendectin. Plaintiffs requested discovery regarding other drugs manufactured by defendant, but the court limited discovery to information concerning the drug plaintiffs ingested. *Id.* The court determined that plaintiffs' expansive request would thwart the civil rules governing discovery:

> [N]ot confining discovery to Bendectin and its components alone or in combination with other components would have necessarily opened all of defendant's drugs to discovery – a result that would be truly oppressive and would thwart any attempt at a just, speedy, or inexpensive determination of the action.

Id. (citing other cases denying discovery of products other than the product issue, *e.g., Uitts v. General Motors Corp.*, 62 F.R.D. 560 (E.D. Pa. 1974) (discovery limited to vehicles identical to vehicle in question)).

Defendants should not be forced to produce every document pertaining to any product manufactured by Actavis Totowa at its Little Falls facility. Those documents are simply irrelevant. As in *Richardson-Merrell*, such limitless discovery would "thwart any attempt at a just, speedy, or inexpensive determination of the action." 624 F. Supp. at 1241. Granting Plaintiffs limitless discovery is not reasonably calculated to lead to the discovery of admissible evidence. Fed. R. Civ. P. 26(b)(1).

The *In re Graco Children's Products, Inc.*, 210 S.W.3d 598 (Tex. 2006) decision provides a solid example of how a problem in product A does not prove a defect in product B. That decision involved an allegedly defective harness buckle in a five-point harness infant car seat. *Id.* at 600. Two weeks before trial, the Consumer Products Safety Commission announced a provisional settlement with Graco imposing a $4 million civil penalty – the largest in the

agency's history – for failing to report defects in more than a dozen products. *Id.* None of these products, however, had five-point harnesses, and none mentioned defective harness buckles. *Id.* The trial court allowed discovery of the unrelated products and defects, which the Texas Supreme Court found to be an abuse of discretion. *Id.* at 600-01. Citing cases in which it granted mandamus when a discovery order covered products the plaintiff never used, the Court stated that there was "no apparent connection between the alleged defect and the discovery ordered." *Id.* at 601. "We agree that Graco cannot defend this case by proving it is generally a good corporate citizen, any more than [plaintiffs] can prosecute it by proving otherwise." *Id.* The court added that "while a corporate defendant's 'state of mind' about a particular product may be discoverable, we have rejected attempts to extend that inquiry to every product it ever made." *Id.*

As in *In re Graco*, the Court should not permit discovery of products that Plaintiffs never used. Additionally, the alleged defect at issue in this litigation is whether any Digitek® tablet was double thick or had too much or too little digoxin. Product defects that do not involve digoxin, or even dosage issues, are "well outside the proper bounds of discovery" as they are entirely irrelevant. *Id.* at 600.

Not surprisingly, Plaintiffs cite no case permitting the limitless discovery they seek here. The one case they do cite – *Marks v. Global Mortgage Group, Inc.*, 218 F.R.D. 492 (S.D. W. Va. 2003) – actually demonstrates how a court should carefully limit the scope of discovery. As this Court is well aware, *Marks* was a predatory lending class action in which plaintiffs alleged that defendants failed to provide disclosures required for balloon notes under West Virginia law. *Id.* at 494. Plaintiffs sought information about other types of loans defendants had issued to other customers, and this Court appropriately limited discovery to balloon notes – the basis of plaintiffs' class allegations. *Id.* at 494, 497. The Court did not permit plaintiffs to acquire every note, contract,

or document that the defendant bank and mortgage company possessed. Similarly here, Defendants request the Court to limit the scope of discovery to Digitek®, the basis of Plaintiffs' Complaint. (ECF No. 73 at ¶¶ 3-9, 12-17, 54-182.)

Last, the mere fact of a recall of all products provides no basis to expand discovery. Plaintiffs must make a showing that discovery as to all of the 106 products would be reasonably calculated to lead to admissible evidence. As established above, they have not; that there were product recalls does not change that result. Indeed, a recall is not even evidence of a product defect. *Perona v. Volkswagen of America, Inc.*, 292 Ill. App.3d 59, 63, 684 N.E.2d 859, 872 (1997) ("A manufacturer recall does not admit a defect in a particular product, but refers to the possibility of a defect in a class of products.") Further, Plaintiffs are prohibited from using a recall of one product as evidence of a defect in another. *Verzwyvelt v. St. Paul Fire & Marine Insurance Company*, 175 F. Supp. 2d 881, 888-89 (W.D. La. 2001) (the defendant "will be unfairly prejudiced and the jury confused or mislead if the plaintiff is permitted to parade before the jury evidence of a product recall and plant closure of a different product").

C. Plaintiffs' Motion to Expand the Scope of Discovery to Include Every Product at the Little Falls Facility Would Involve Tremendous Cost, With No Benefit to this Litigation, and Would Substantially Delay These Proceedings.

To date, Defendants have spent approximately $4,500,000 gathering and producing documents in this litigation pertaining to Digitek®. (*See* Affidavit of Alan Winchester ¶ 7, Exh. C.) It is anticipated they will spend another $1,500,000 to complete production. (*Id.* at ¶ 9.) If forced to gather and produce documents pertaining to the 106 other products manufactured at the Little Falls facility, Defendants would incur "three to five times that expense." (*Id.*, ¶ 11.) This staggering cost would be unduly burdensome, and the result would be the production of

irrelevant and ultimately inadmissible documents. *See Murphy v. Cooper Tire & Rubber Co.*, 2008 WL 5273548, at *5-6 (N.D. Fla. Dec. 18, 2008) (denying plaintiffs' requests to discover information concerning every model tire made at defendant's plant because 1) plaintiffs had not shown that the other tire models were substantially similar to the one tire model in question, and 2) collecting over 5 million pages of documents would be unduly burdensome); *Lawrence E. Jaffee Pension Plan v. Household Intern., Inc.*, 2006 WL 3445742 (N.D. Ill. Nov. 22, 2006) (denying discovery of marginally probative evidence where defendants had already produced 4 million pages of documents and the burden on defendants of further production would be immense).

As to timing, Defendants are now producing documents in accordance with PTO #16. To add 106 drugs would require – at a minimum – twelve additional months. (Winchester Aff. ¶ 12.) That would put the time table of the MDL substantially behind the state court litigation where such requests have not been made.

IV. CONCLUSION

There is no mistaking what Plaintiffs are requesting: limitless discovery of matters far outside the scope of this litigation. This is precluded under PTO #12 and FRE 401 relevancy principles. Under these standards, Plaintiffs are limited to Digitek® documents and may not "fish" in non-Digitek® documents. For these reasons, Defendants Actavis Totowa LLC, Actavis

Inc., and Actavis Elizabeth, LLC request that the Court deny Plaintiffs' Motion to Expand the Scope of Discovery and grant their Motion to Quash the Gibraltar Subpoena.

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CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2009, a copy of the foregoing Defendants' Brief in Opposition to Plaintiffs' Motion to Expand and Define the Scope of Discovery was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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EXHIBIT A

SUPERIOR COURT OF NEW JERSEY
BERGEN COUNTY
LAW DIVISION, CIVIL PART
DOCKET NO. L-917-09
APP. DIV. NO._____

STATE OF NEW JERSEY)
)
IN RE:)
)
DIGITEK LITIGATION)
)

TRANSCRIPT
of
CASE MANAGEMENT CONFERENCE

Place: Bergen Co. Justice Ctr.
10 Main Street
Hackensack, NJ 07601

Date: March 27, 2009

BEFORE:

HONORABLE JONATHAN N. HARRIS, J.S.C.

TRANSCRIPT ORDERED BY:

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I N D E X

THE COURT: This is IN RE: DIGITEK LITIGATION under Master Docket No. L-917-09. May I have the appearances of counsel.
MS. RELKIN: Ellen Relkin from Weitz and Luxenberg for several plaintiffs.
MR. WEINKOWITZ: Mike Weinkowitz from Levin, Fishbein for several plaintiffs.
THE COURT: Counsel, would you spell your last name, please.
MR. WEINKOWITZ: W-E-I-N-K-O-W-I-T-Z.
THE COURT: Thank you.
MR. GRAND: Jeff Grand from -- from Seeger Weiss for several plaintiffs.
THE COURT: I couldn't hear you.
MR. GRAND: Jeff Grand.
THE COURT: Grant?
MR. GRAND: Grand, G-R-A-N-D as in David, from Seeger Weiss, for the plaintiffs.
THE COURT: Thank you.
MR. STADTMAUER: Steven Stadtmauer, S-T-A-D-T-M-A-U-E-R, Harris Beach, for defendants, and I'd like to introduce several pro hac attorneys for defendants.
MR. DEAN: My name is Richard Dean, Your Honor, D-E-A-N, and I represent the Actavis defendants.
MR. TABER: Your Honor, I'm Ed Taber from

Cleveland, Ohio. I work with Dick at Tucker Ellis and West. My last name is spelled T-A-B-E-R, for all of the Actavis defendants.
MS. WEST: Your Honor, Sarah West with Shook, Hardy, and Bacon, Kansas City, for the Mylan defendants.
THE COURT: Counsel, I didn't hear you.
MS. WEST: Sorry.
THE COURT: Would you spell your last name.
MS. WEST: West, W-E-S-T.
THE COURT: Thank you.
MS. DOWNIE: Good morning, Your Honor, Ericka Downie from Shook, Hardy, and Bacon on behalf of the Mylan defendants.
MS. WEST: And, Your Honor, there's some additional plaintiffs' counsel right here.
THE COURT: Does anybody else wish to have their appearances noted for the record?
MR. PETTIT: Yes, Your Honor, James Pettit, P-E-T-T-I-T, the Locks Law Firm, for plaintiffs, several plaintiffs.
MR. LAPINSKI: Good morning, Your Honor, Daniel Lapinski of the Wilentz law firm in Woodbridge, New Jersey for plaintiffs.
MR. GALEX: Good morning, Richard Galex,

Galex Wolf, on behalf of Carol Millroad (phonetic).

THE COURT: Good morning to everybody and welcome. Probably the most important information that you're going to receive today is to be introduced to the mass tort team and status keepers, which is not me, I just resolve the disputes, it's the people that are going to help with the management, and that's the women sitting in the jury box, Francesca (phonetic), Michelle, and Genevieve (phonetic), and I'm sure that over time you'll learn to take their counsel and to bounce ideas off of them without worrying about engaging in any -- in any ex parte communications with me because I know you're not going to do it and I'm not going to do it.

But any conversations you have with members of this staff is fair game, so to speak, and they're here to help you as much as to assist me.

I'm going to start at a place that I usually don't start, only because of almost the inevitability factor in these cases, and that is -- and don't misunderstand that I'm trying to rush something because I'm not, when will it be appropriate to discuss, either with or without the Court, mediation and settlement of these cases.

And I say that because when I talk about the

inevitability factor, this case may be an exception and maybe we'll try 41 cases or maybe we won't, and I'm not doing it for my sake, because I've got plenty of limited resources to manage this case with all of the other mass torts that are in my inventory, I'm saying it for your clients' sake.

And I'm not looking at one side or the other because I don't pretend to know the subtleties of the case or the details, other than the broad picture, and I'm not comparing this case to any other centrally-managed matter or otherwise.

But it usually serves the parties' better interests to get into that modality sooner rather than later, but there is an appropriate time, and that time I'm not suggesting is today but I'd like the parties to keep in mind that in a conservation of resources mind set, sooner rather than later is always the best route to go.

I will say, as well, that I've had, I'm pausing to remember, at least one short conversation with the MDL in West Virginia that was within days of the Supreme Court's reference of these cases to me, so it was not substantive in any regard.

I believe that he called me, we exchanged pleasantries, he congratulated me, and I indicated to

just want you to be aware that there will be that significant document production in the near future.

Now the other thing I would say, just give you highlights of, we have -- we have worked I think in good cooperation with the plaintiffs' counsel in this case, in a number of meet and confers, several in person and several by telephone.

What we have focused on -- let me tell you what we've focused on and what we have -- what we have not focused on simply because of time constraints. We clearly have been focusing on issues on the protective order and on the plaintiff fact sheets and the defendant fact sheets.

What we really have not addressed at -- in any significant depth, other than the barest of discussions is we have not really talked to each other about a case management order, a scheduling order. We have not talked about electronic discovery. We have not talked about culling terms. We have not talked about preservation orders in any depth. All -- obviously preservation orders are in place in the federal litigation.

But just to give you a flavor of what we have done and what we have not done, that is I think the highlights of the discussions between us and

plaintiffs' counsel so far.

There was a brief reference, let me just comment for one minute, on tolling agreements. We have taken the position that we would not engage or we would not enter into an across the board broad brush set of tolling agreements.

However, we have told plaintiffs' counsel if they get into a -- this -- this -- I guess it didn't happen in this state but in other states there may be statute of limitations issues coming up, and we have told plaintiffs' lawyers that we have a group of cases where you want to come to us, talk about specific cases with the tolling agreement, we'll talk to you about specific cases.

We don't want to do a broad across-the-board agreement on tolling agreements. We would -- for reasons as -- kind of similar to what you articulated, we do see a value in knowing what the universe is and getting -- getting that universe on file and knowing what we're dealing with.

Then I think Ms. Relkin made brief reference to the fact that -- you were talking about the testing issue and whether any testing had been done. Ms. Relkin made reference to the fact that she had heard that tests had been done where out of spec results came

back.
If indeed that has happened, nobody has -- no plaintiffs' lawyer has provided that to us. What we have done, Your Honor, is that we have -- many plaintiffs' lawyers understandably want to know whether they have any double-thick tablets.
These are very small tablets, so just by -- just to an untrained observer, it would be hard to tell whether they were double thick or not. So we have gone out to a number of plaintiffs' lawyers before who wanted us to come and weigh and measure their tablets to see if they had any double-thick tablets, all of this on an informal discovery track, nothing formal, and this is outside of New Jersey. I don't want -- I want to make that clear.
We've visited probably the offices of 20 different plaintiffs' lawyers. We have -- we have not yet seen any double-thick tablet. Now obviously you heard the statement made to you this morning, well, we may pursue a claim that a regular-size tablet without a specification, that is going to be an extremely difficult case to prove.
Frankly, I think the best way, the only way really to prove that would be to test tablets and see what the results -- what the results were. This

litigation started out as, was at least generated, initial filings were generated by the concept or the thought that they were double-thick tablets out on the market.
We believe our records will demonstrate, and obviously the plaintiffs have a right to look at them, they don't have to take my word for it, but we -- we believe that the only double-thick tablets were one lot and that they were found before they were -- they were shipped to market.
So the bottom line is we have not --
THE COURT: Have you ever seen the double-thick --
MR. DEAN: No, I have not.
THE COURT: -- tablet?
MR. DEAN: I have not.
THE COURT: Is that like the upside down plane on the stamp, if you can find one, you're very --
MR. DEAN: Yeah, you've won -- you've won the big prize. You asked a very --
THE COURT: Well, let me -- I apologize for interrupting.
MR. DEAN: Sure.
THE COURT: Have any plaintiffs' counsel seen this elusive double-thick tablet or any -- do you know

of any experts who have, or doctors, or pharmacists, or is it the quark?

MR. WEINKOWITZ: Your Honor, I'm not aware of any -- that I have not looked at any tablets myself, so I'm not aware of any. I'm not aware of whether anybody else has.

But double thick from our perspective, is a red herring. A pill can have more than or less than the amount of the active ingredient in Digoxin even if it's not twice as thick, and indeed, the FDA recall and the announcement of the recall did -- went beyond just double-thick tablets to talk about dosing.

So the defendants like to keep framing the issues double thick, double thick, double thick. I could have a bunch of tablets on my table and none of them could be double thick but that's not the point.

THE COURT: Well, did -- did I hear you represent before or if it was Ms. Relkin, I forget, that there is forensic evidence, maybe incomplete and I appreciate that, that would suggest that at least one tablet somewhere, maybe more, whether it's double thick or not is beside the fact, it has out-of-specification dosage?

MR. WEINKOWITZ: Well, I'll tell you exactly and Ellen can tell you what she heard. This is what I

have heard in telephone discussions about this case, that someone has done testing of the tab-- of Digitek tablets, I don't know whether there were a plaintiff's or not a plaintiff's, I don't know that, and that there have been -- what has been discovered is too much Digoxin and too little Digoxin, outside of what I understand is the variances that are allowed to -- that the tablets are allowed to have.

That -- I heard that. I don't know who's done the testing. I don't even know who --

THE COURT: Wouldn't that be something that I'm not suggesting you'd need that to file your lawsuit, far from it, but wouldn't that be something that you'd want to get your arms around as fast as possible? Because if there are --

MR. WEINKOWITZ: What I --

THE COURT: Because if there are other recognized ways of suffering Digoxin toxicity, it's a question of risk and benefit analysis of going forward with the lawsuit. I'm not trying to talk you out of it, --

MR. WEINKOWITZ: Right.

THE COURT: -- far from it, --

MR. WEINKOWITZ: Right.

THE COURT: -- but I would think that if in

fact there is this what's now anecdotal evidence out there, plaintiffs would either want to urge me to get the plaintiffs right away to be able to do their own testing or collect from colleagues what this anecdotal evidence is.

MR. WEINKOWITZ: And --

THE COURT: Don't take that as a criticism, but --

MR. WEINKOWITZ: No, no, I understand, and what I want as a plaintiff's lawyer to get my hands around is what happened at that plant that wasn't in FDA compliance, why were those pills recalled, what testing was done, how much, what did they find. I understand the --

THE COURT: Well, I must say that sounds like the archetypical fishing expedition.

MR. WEINKOWITZ: Well, Your Honor, I --

THE COURT: I mean, you could -- you could just as easily say about any drug manufacturer.

MR. WEINKOWITZ: Yeah, but not any -- any drug manufacturers had --

THE COURT: Well, lots of people have adverse drug effects --

MR. WEINKOWITZ: Yeah, but they didn't have --

THE COURT: -- and they go a plaintiff's lawyer and say gee, I had a bad incident here, test it, oh, my God, you have Coumadin poisoning, well, now I want to go into the Coumadin plant, I want to check all of their warfarin specifications.

I mean, it sounds absurd and silly, but I think you'd want a little bit more than you've got here. I'm not suggesting you're acting in bad faith but, you know, a lot of whispers are in the wind in this thing that don't really mean too much.

MR. WEINKOWITZ: Your Honor, in the scenario -- I understand what you're saying in the scenario that you came in. There -- here we have an FDA recall involving tablets that had too much --

THE COURT: I must tell you that I don't put much stock in an FDA recall as being anything.

MR. WEINKOWITZ: And we have a plant that closed down and was cited twice for violations of good manufacturing process, and that plant has never opened back up, and in fact, the defendants had to recall all of their generic drugs other than Digoxin from that plant because of bad manufacturing process.

So with -- with all due respect, I think here we have --

THE COURT: Well, if you think that you can

convince a trier of the fact using that type of circumstantial evidence, I think that you need to re-think it, and I'm sure you wouldn't go to a jury with just that, you'd go to a jury with the specifics of the tablets. That's all I'm pointing out.

That ought to be something that plaintiffs were to get -- get involved with sooner rather than later. And I'm not suggesting, I'm not going to allow what I'll call free-ranging discovery, but I think it's starting to sound, and I'm just beginning to learn the subtleties and I'm probably going to misapprehend them today, that it may ultimately be counterproductive if in fact every ounce, every dollar that goes into defense costs potentially makes smaller the potential pool of a settlement.

You know, I think you really need to see what you've got rather than, you know, FDA did something, we're going to jump on that bandwagon. I mean, that could turn out to be a dead end. I don't want to hear anymore of this. I want to get back to this.

Mr. Dean.

MR. DEAN: Just a couple of more items, Your Honor. You asked a -- I think a question that really cuts to the heart of the litigation. The question you asked was -- of plaintiffs was is Digoxin toxicity

caused by oversized tablets.

Well, the answer to that is Digoxin toxicity could well be caused by oversized tablets but the problem with the plaintiff, with the causation in this case is that Digoxin toxicity can also be caused by absolutely perfectly normal tablets.

You can have a tablet that's absolutely to specification and somebody can be taking it for let's say six months and they can be fine today and then may have a chance in their kidney function or may have a change in their metabolism and their Digoxin level can go up not because anything is wrong with the tablet but simply by what's happening within their body.

So their -- that, as you can appreciate, makes proof of causation in a specific case unbelievably -- unbelievably difficult. So the answer to your question could a double-sized tablet cause toxicity, I think if you took enough of them the answer is yes, but the conundrum here is that if you took perfectly normal tablets, under certain circumstances you can also end up with Digoxin toxicity.

I think in the material we provided to Your Honor we quoted from the package insert on -- on Digitek and it basically says you've got to look at what's going on in the patient, you can't be slandishly

adherent to a lab value and not look at what's happening physically with the patient because you can't just look at -- you can't just look at a level.

And you can have tox-- you can have Digoxin toxicity with perfectly normal tablets.

THE COURT: Well, the questions of general causation and specific causation --

MR. DEAN: Right.

THE COURT: -- I think are true in all of these cases. There's nothing new and different here. I mean, not every person who ingested Fen-phen --

MR. DEAN: Right.

THE COURT: -- had heart problems.

MR. DEAN: My point is if you get a -- if let's say we get a medical record that somebody has what on its face would look like a high Digoxin level, that doesn't mean that they got a double-thick tablet. That simply may mean they had changes within their body which resulted in an increased value.

THE COURT: Well, it also may mean that the factory was doing something wrong but less than double thickness and distributing out-of-specification tablets that hopefully somebody can proximately link back to the injuries.

MR. DEAN: Yeah, and --

THE COURT: The fact -- the fact that it may be, I think you used this word, extraordinarily difficult to prove, is something the plaintiffs have to evaluate.

MR. DEAN: Certainly. And just I would also comment because I think Ms. Relkin mentioned this and I just wanted to confirm this point, that as to all of the lots that were recalled, there are retained samples, and we have the retained samples on each of these lots that was recalled, so those are -- those are available for -- for testing, as well.

THE COURT: What do FDA regulations provide, if anything, or any orders of the agency in this case relating to testing of recalled materials?

MR. DEAN: I'm not an FDA regulatory lawyer, but I think I know the answer to that question. I think the answer to that question is that the FDA regulations simply provide that the product be returned, gotten off the market, and retained.

I don't think those regulations mandate or call for any testing of the recalled product.

THE COURT: Are there any agency standstill orders, for example, to prevent testing, or are any applications going to be necessary to the agency before testing is conducted, either at plaintiffs' insistence,

or at defendants' assistance, or at the Court's permission?

MR. DEAN: That's an excellent question, too. I -- I'm not aware of any standstill orders, but obviously since Stericycle is under FDA supervision, before any tablets were tested there, we'd have to make sure we weren't doing anything adverse to the FDA.

I think we can work through that if there are, but I'm not aware of any --

THE COURT: Well, what --

MR. DEAN: -- standstill --

THE COURT: What comfort can you give the plaintiffs that you haven't already given, and maybe I'm too paranoid for my own good, what comfort can you give me that when it's time, if there comes a time, to examine these tablets or some random sample or whatever, Stericycle will produce them?

I mean, just because there's a contract, you know, as lawyers that may give some comfort but I wouldn't take too much comfort in it. Stericycle is not a party to this case, is not going to -- not bound -- and I take it is not bound, but I don't know, to do anything or refrain from doing anything in the MDL, or if it is, somebody should tell me.

And it's not because I have any knowledge of

Stericycle, but whenever the object of the litigation, the res, R-E-S, is in somebody else's hands, forget about that it's not within this jurisdiction, everybody ought to have some concern about that.

And if I'm the only one who has concern of it, then I won't lose any sleep over it, but if I can help in any way, I want to do that. Maybe it doesn't need help. Do you understand my question?

MR. DEAN: I do indeed and let me -- I think it's again an excellent question, and I -- I have, here's -- here's what I would have, I would be uncomfortable about, I'm not uncomfortable about Stericycle because they have an FDA mandate to hold onto that stuff.

THE COURT: Well, --

MR. DEAN: They --

THE COURT: -- Bernie Madoff had an SEC obligation, too, --

MR. DEAN: Well, --

THE COURT: -- maybe.

MR. DEAN: -- at least there's -- at least there's a regular-- at least -- I can represent to you they're holding onto it and I can represent to you that there are FDA regulations. We have heard today that we have -- we have individual plaintiffs in New Jersey

EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

AFFIDAVIT OF RICHARD DOWLING

STATE OF NEW JERSEY)
) SS
COUNTY OF MORRIS)

1. My name is Richard Dowling. I was formerly the Director of Manufacturing Operations for Actavis Totowa LLC at the Little Falls, New Jersey facility ("Little Falls facility"). My current job title is Director of Manufacturing Compliance for the Actavis Totowa LLC Little Falls, New Jersey facility. I have been with Actavis Totowa since October, 2005.

2. I have worked in the pharmaceutical industry for approximately 32 years. For the past 14 years, my experience has been with solid dose forms operations.

3. From October, 2005, through May, 2008, I had responsibility for all manufacturing floor operations at the Little Falls facility. Because of my job responsibilities, I have personal knowledge of all aspects of the manufacture and production of Digitek® and of all the products Actavis Totowa has produced at the Little Falls facility since October, 2005, including: raw material storage, plant layout, blending processes, blend mixture storage, tablet compression, encapsulation, storage of tablets and capsules, and the cleaning and preventative maintenance of all of the equipment utilized by Actavis Totowa in any aspect of these processes.

4. For all pharmaceutical products manufactured at the Little Falls facility, Actavis Totowa keeps and maintains what are known as batch records. Batch records, the primary method for documenting the manufacturing process, are documents which contain information about each stage of the manufacturing process.

5. Digitek® is the trade name for Actavis Totowa's generic form of the cardiac medication digoxin. Until April, 2008, Digitek® was manufactured at the Little Falls facility in two dose strengths: 0.125 mg and 0.25 mg. These two Digitek® dose strengths are considered to be separate products.

6. In addition to the two Digitek® dose strengths, Actavis Totowa made 106 other products at the Little Falls facility, consisting of 64 unique drugs in various dose strengths, until May, 2008, when Actavis discontinued all manufacturing operations at the Little Falls facility.

7. The manufacturing process for each of the 64 unique drug products manufactured at the Little Falls facility is different and distinct from the manufacturing process for every other drug manufactured at the Little Falls facility. Every product manufactured at the Little Falls facility has its own unique manufacturing and packaging procedures and protocols/batch records that are developed and used exclusively for that product. No production procedures and protocols/batch records for any two different drugs are the same.

8. Digitek® is produced according to detailed manufacturing and packaging protocols/batch records and procedures designed specifically for and used exclusively to manufacture Digitek®. These protocols are reviewed and approved by the FDA as part of its regulatory oversight of Actavis Totowa.

9. The manufacture of Digitek® is a distinct process that involves a unique set of ingredients, specifications, and equipment.

10. The active pharmaceutical ingredient for Digitek® – digoxin – is not included in any other product manufactured at the Little Falls facility. There is no opportunity for Digitek® to be mistaken with or cross contaminated by some other digoxin product.

11. Every aspect of Digitek® raw material storage is distinct from other products made at the Little Falls facility. Digoxin is received in approximately 1 kg sealed plastic bottles; except for the active pharmaceutical ingredient for one other product, all other active pharmaceutical ingredients were received in fiber drums.

12. The other ingredients of Digitek® are corn starch, croscarmellose sodium, lactose hydrous impalpable, starch pregelatinized, mircrocrystalline cellulose, lactose anhydrous, stearic acid, and silicon dioxide. The combination, weight, and blend uniformity of these raw materials is unique to Digitek®.

13. Actavis Totowa's manufacturing protocols/batch records identify the specific equipment to be utilized to produce each product. The combination of equipment used is unique to each product. At the beginning of each stage of the manufacturing and production process, each piece of equipment relevant to that stage of manufacturing for that product is carefully identified in batch-specific records.

14. Digitek® is produced using what effectively is a custom, Digitek®-only tablet press. The base model and make of the tablet press used to manufacture all of the recalled Digitek® is a 45 station Stokes BB2 tablet press. Each time Digitek® is manufactured, the Stokes BB2 45 station press is customized using very unique "tooling" – punches and dies – designed solely and used exclusively for the purpose of manufacturing Digitek® on that tablet press.

15. The tablets are pressed by a machine using rotating "punches" – an upper punch and a lower punch – that come together in a cast "die" – effectively the mold of the tablet – to compress powder into a tablet.

16. The dies are custom designed to produce the correct sized tablets, depending on dose strength, and are used solely and exclusively to make Digitek®.

17. The punches are custom designed and are used solely and exclusively to make Digitek® – the upper punch contains the appropriate marking on the tip so each tablet pressed with that punch becomes embossed with the appropriate label corresponding to its product identification number ("145" (0.125 mg dose strength) or "146" (0.25 mg dose strength)) when it is pressed.

18. This unique tooling is not used for any other product. It is physically removed from the tablet press and stored in a specific numbered container when Digitek® is not being manufactured and is retrieved from storage and physically installed in the tablet press when Digitek® is going to be made. In addition, logs exist that track the tooling usage by batch, and the physical inspection of the tooling.

19. The tablet press cannot function without tooling. Each product manufactured using that tablet press has its own custom designed unique tooling that is retrieved from a specific numbered storage container and installed in the machine before the product is made – even the tooling for the 0.125 mg dose strength of Digitek® is different than the tooling for the 0.25 mg dose strength of Digitek®.

20. Because of the different tooling for each product manufactured on any given machine, effectively a different tablet press is used to make Digitek® than is used to make any other product.

21. Digitek® 0.125mg is a yellow, 1/4" flat face beveled edge tablet. Only one other product manufactured at the Little Falls facility has tooling that is the same size as the tooling used

to make the recalled 0.125mg Digitek®, and this other product is a bisected tablet that was not produced on a 45 station Stokes BB2 tablet press.

22. Digitek® 0.250mg is a white, 9/32" standard concave round tablet. Only four other products manufactured at the Little Falls facility have tooling that is the same size tooling as the tooling used to make the recalled 0.25mg Digitek®. These other products are distinct from Digitek®: One product is bisected in the center and is not produced using a 45 station Stokes BB2 tablet press; two of the other products are film coated after compression with an orange color; and one of the other products is a yellow tablet.

23. At the end of the manufacturing process for each specific product campaign, all of the equipment used during the various stages of the manufacturing or packaging process for that product is broken down and disassembled, in accordance with equipment-specific procedures. Each part is thoroughly cleaned and, where appropriate, sanitized. The cleaning is carefully logged in a cleaning log. No equipment is used to manufacture a different product unless and until it has been cleaned and, where appropriate, sanitized and then visually inspected for cleanliness.

24. At the beginning of the manufacturing process for the next product manufactured on any given piece of equipment, the clean, sanitized components of that piece of equipment are reassembled during the "set-up" process for the new product campaign.

25. After the clean, sterilized parts of a piece of equipment are reassembled, each piece of equipment is tested and precisely calibrated to achieve and demonstrate compliance with the manufacturing batch record specifications before the new product is produced – all product produced during this set-up phase is destroyed and all such waste is monitored and tracked. No

new product is manufactured until the equipment is properly set up and calibrated to achieve compliance with manufacturing specifications.

26. All of the equipment set-up and calibration activity is carefully documented in batch-specific records.

27. In the process of blending Digitek®, three blenders are used – a V-shaped blender, a portable blender, and a 50 cubic foot blender and the Digitek® blending process involves the weighing and mixing of three pre-blends that are combined in one final blend in the 50 cubic foot blender. Digitek® was blended in room 117. Digitek® was pressed into tablets in rooms 119 and 120.

28. During 2005-2008, there was very little overlap between the equipment used to make Digitek® and the equipment used to make any of the other 106 products manufactured at the Little Falls facility.

29. From 2005-2008, in any given year, no more than 14 other products were blended in the same room where Digitek® was blended.

30. From 2005-2008, in any given year, no more than 10 other products used the V-shaped blender that was used in the Digitek® blending process.

31. From 2005-2008, the portable blender that was used in the Digitek® blending process was used exclusively to blend Digitek® and was not used in the blending process for any of the 106 other products manufactured at the Little Falls facility during that time period.

32. From 2005-2008, in any given year, the 50 cubic foot blender that was used in the Digitek® blending process was used to blend only one other product other than Digitek®.

33. No other product manufactured at the Little Falls facility during 2005-2008 has three pre-blends.

34. From 2005-2008, in any given year, only six products other than Digitek® were pressed in either Room 119 or Room 120.

35. Digitek® was the only finished product in the facility stored prior to packaging in white, square plastic buckets with snap-on lids.

36. Of the 106 products manufactured at the Little Falls facility during 2005-2008, 96 products required use of no equipment in the manufacturing process that also was used to make either 0.125 mg dose strength Digitek® or 0.25 mg dose strength of Digitek®.

37. Once a specific phase of the Digitek® production process begins – blending, compression, packaging – Quality Assurance and Quality Control checks are performed for various product characteristics pursuant to strict protocols. The results are carefully logged in batch-specific data sheets.

38. After blending but before the mixture is compressed into tablets, the final blend is tested for blend uniformity, using specifications that are unique to Digitek®.

39. At the compression stage, the press operator and the quality assurance employees inspect Digitek® tablets for visual appearance, including weight, thickness, and hardness, using specifications that are unique to Digitek®.

40. Laboratory testing of batch-specific Digitek® product samples occurs during the manufacture of each batch in accordance with strict product-specific protocols. The results of the laboratory testing are documented in batch-specific records.

41. Digitek® tablets are dissolved and chemically tested to check for dose uniformity and stability using specifications that are unique to Digitek®. The results are documented in batch-specific records.

42. Essentially, each time a product is manufactured at the Little Falls facility, Actavis Totowa starts the manufacturing process from scratch with clean, newly reassembled and calibrated equipment. Each new batch of each new product is essentially a separate manufacturing process unto itself.

43. Data and information relating to any drug other than Digitek® will provide no insight into any aspect or characteristic of the manufacture of any Digitek® batch. The only documents that will provide information indicating whether there was a problem with any aspect of the manufacturing process for any batch of Digitek® are the documents relating to Digitek®.

44. In my experience during my 32 years in the pharmaceutical industry, it is not a common practice for a pharmaceutical manufacturer to have dedicated personnel or "teams" assigned to manufacture only one product. In most instances, pharmaceutical manufacturers have groups of employees who are trained to perform a certain function or group of functions and those employees then perform the functions for which they are hired and trained on various products that are manufactured by that company. For example, an individual who is trained to operate a tablet press typically will operate a tablet press for any product being manufactured by that company using a tablet press and will not usually press tablets only for one product.

FURTHER AFFIANT SAYETH NAUGHT.

RICHARD DOWLING

SWORN TO BEFORE ME AND SUBSCRIBED in my presence this 22nd day of June, 2009.

NOTARY PUBLIC
Attorney at Law

EXHIBIT C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK® PRODUCT LIABILITY LITIGATION **MDL NO. 1968**

AFFIDAVIT OF ALAN M. WINCHESTER

STATE OF NEW YORK)
) SS
COUNTY OF NEW YORK)

Alan M. Winchester, Esq., being duly sworn according to law, deposes and says as follows:

1. I am a member of Harris Beach PLLC and the leader of the firm's electronic discovery practice group.

2. Harris Beach serves as document counsel for the Actavis Defendants ("Actavis"), Mylan, and UDL in connection with the claims in the Digitek® litigation – alleging personal injury as a result of dosage issues associated with the pharmaceutical product Digitek®. In that capacity, Harris Beach is responsible for providing counsel on the process of producing documents to Plaintiffs. Producing documents includes the preservation, collection, processing, and production of both paper documents and electronic documents.

3. Digitek® is manufactured by Actavis Totowa LLC ("Actavis Totowa") in two dose strengths – 0.125 mg and 0.25 mg. These two dose strengths are considered to

be two of 108 pharmaceutical products manufactured and sold by Actavis Totowa at its Little Falls, New Jersey facility until May, 2008.

4. According to the protocol mutually established between Plaintiffs and Defendants in this litigation, and recorded by the Court in a Pretrial Order, all documents Defendants will produce to Plaintiffs are being produced in a certain specified electronic format called "Tiff." In the ordinary course, documents are not created or stored in the format the parties have agreed to for purposes of this litigation. Paper documents are stored in hard-copy form and electronic documents are created and stored in what is commonly referred to as their "native" format. Before a paper document or electronic document can be reviewed by an attorney for possible relevance, and then prepared for production to Plaintiffs, it must be processed and formatted for the review platform upon which the reviewers will conduct their review. Once the potentially relevant and responsive documents have been reviewed, they must then be processed and placed into the agreed-upon production format. These steps are commonly referred to as "processing" documents for production.

5. As of June 18, 2009, Defendants have focused their document collection, processing, and production activities on paper and electronic documents primarily related to Digitek®, since this is the only pharmaceutical product identified in Plaintiffs' personal injury claims in the Digitek® Litigation.

6. As of June 18, 2009, the Defendants have collected 19.1 terabytes of content, comprised of more than 31,000,000 documents.

7. As of June 18, 2009 the fees and costs incurred by Defendants solely from Harris Beach in connection with producing documents is more than $4,500,000. The attorney and paraprofessional component of that sum is $169,000 and the remainder is costs associated with processing and hosting the documents collected to date.

8. A team of Information Technology professionals have been working for approximately 12 months, spending thousands of man hours, to process the 19 terabytes of information and data that has been collected as potentially relevant to Digitek® and prepare it to be reviewed for possible production to Plaintiffs.

9. We anticipate that Defendants will incur future expenses of approximately $1,500,000 to continue hosting Digitek®-related documents and produce responsive documents if the scope of discovery remains as it is currently defined, limited primarily to Digitek®-related documents.

10. The amounts set forth in paragraphs 7 and 9 do not include the fees and costs associated with attorney review of documents to determine which documents are responsive and identify documents that are privileged, which is being performed by attorneys at Tucker Ellis & West LLP and an outside third-party vendor on behalf of Actavis, and by Shook Hardy and Bacon on behalf of Mylan and UDL.

11. If the scope of discovery were expanded to include all of the 106 other pharmaceuticals manufactured by Actavis Totowa at its Little Falls facility until May, 2008, assuming Defendants were required to collect, process, and review all documents relating to all non-Digitek® products manufactured at the Little Falls facility, Defendants would incur additional document production expenses of approximately three to five

times the $4,500,000 they already have incurred exclusive of the attorney time to review the additional documents.

12. If the scope of discovery were expanded to include all of the 106 other pharmaceuticals manufactured by Actavis Totowa at its Little Falls facility until May, 2008, assuming Defendants were required to collect, process, and review all documents relating to all non-Digitek® products manufactured at the Little Falls facility, it would take at least 12 months, and likely longer, from the date Defendants started collecting, processing, and reviewing documents, for Defendants to complete their document production.

FURTHER AFFIANT SAYETH NAUGHT.

ALAN M. WINCHESTER

SWORN TO BEFORE ME AND SUBSCRIBED in my presence this 22nd day of June, 2009.

NOTARY PUBLIC

SOCRATES SCOTT L. NICHOLAS
Notary Public, State of New York
No. 60-4784084
Qualified in New York County
Commission Expires February 7, 2010